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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/696,174

10/29/2003

Swaminathan Jayaraman

795-A03-004

7393

33771 7590 09/27/2007
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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

09/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/696,174

Applicant(s)

JAYARAMAN, SWAMINATHAN

Examiner

Brian E. Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-61, 64 and 67-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54-61, 64 and 67-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/9/07 has been entered.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 54,56-59,64,68 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolff et al. (WO 91/12779). Figs. 1,17 show a plurality of stent performs **12** to form a stent **10**. Fig. 4 shows a stent perform with a metallic core **22** and an outer sheath **14** disposed about the contact surface. It can be seen (Figs. 12,15,17) that end caps exist on the core to encapsulate the ends of the wire. Wolff discloses the sheath on the metallic core can include a therapeutic agent, page 10, lines 35,36. Wolff et al. also disclose that the sheath is a polymer and can be bioabsorbable, page 12, lines 16-18. It is inherent there is pores in the sheath or coating since it allows for elution of the drug,

page 10, lines 36-38. Additionally, Wolff discloses two therapeutic agents could be used, page 15, lines 19,20.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff et al. WO 91/12779 in view of Liprie et al. (6491662). Wolff et al. is explained supra. Wolff does disclose the stent can be made from self-expanding material, page 10, line 27. However, Wolff fails to explicitly disclose the core stent material is made of shape memory alloy. Liprie et al. teach that a core is made of shape memory alloy to strengthen the vascular device, col. 2, lines 36-43. It would have been obvious to one of ordinary skill in the art to substitute metal materials and use a SMA as taught by Liprie with the stent of Wolff et al. such that it is flexible enough for delivery through a tortuous vessel, but stiff enough to not crimp.

Claims 60,61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff et al. (WO 91/12779) in view of Barclay et al. (2002/77693). Wolff et al. is explained supra. Wolff et al. does disclose multiple polymer layers can be used, Fig. 3B and page 15, lines 11-21. However, Wolff et al. fail to disclose the drug is coated over the sheath and also using a release layer. Barclay et al. teach (Fig. 5E) a stent **139** can have an outer sheath **141A** and then a drug layer **147** and then a release layer **143**. This enables the drug to be delivered to the lumen tissue and not the blood. It would

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have been obvious to place the drug layer on a sheath layer and then a release layer of polymer on the stent as taught by Barclay et al. with the stent filaments of Wolff et al. such that it can treat the lumen.

Claims 67,69 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff et al. (WO 91/12779) in view of Sukhatme (2005/261283). Wolff et al. is explained supra. Wolff does teach combinations of drugs can be used, page 17, line 14. However, Wolff et al. fail to disclose the drug is selected from cyclosporine A, imatinib mesylate, curcumin, and rapamycin. Sukhatme also teaches that rapamycin and imatinib mesylate can be used to effectively treat hyperplasia, paragraphs 117,151,164. It would have been obvious to one of ordinary skill in the art to utilize the teachings of Sukhatme of combining drugs such as rapamycin with the drug imatinib mesylate to be used in the stent of Wolff et al. to treat vascular disease such as restenosis.

Response to Arguments

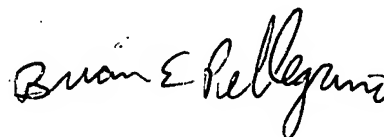
Applicant's arguments with respect to claims 54-61,64,67-69 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on Monday-Friday from 7:30am to 5pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

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supervisor, Corrine McDermott, can be reached at 571-272-4756. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



BRIAN E. PELLEGRINO
PRIMARY EXAMINER

TC 3700, AU 3738